REMARKS/ARGUMENTS

The rejections presented in the Office Action dated August 7, 2006 (hereinafter Office Action) have been considered. Claims 1-45 are pending in the application. Claims 1-17, 24, 25, 29-37, and 43-45 have been rejected. The Examiner has indicated that claims 3-7, 9, 12, 13, 18-23, 26-29 and 38-42 are directed to allowable subject matter. Claims 9, 12, 13, 21 and 38-42 have been canceled without prejudice or disclaimer.

The claims have been amended to incorporate allowable subject matter into the rejected base claims in order to advance prosecution of the allowable subject matter identified by the Examiner. Consideration of the pending claims as amended and allowance of the application in view of the present response is respectfully requested.

Claim 1 has been amended to include features of allowable claims 9, 12, 13, 22, 26, and 27. Claim 17 has been amended to include features of allowable claim 21. Claim 32 has been amended to include features of allowable claims 38-42.

The Applicant reserves the right to continue prosecution of the originally presented claims in a continuation applicant. In anticipation of doing so, and notwithstanding the present amendments to the pending claims, the Applicant traverses the rejections of record and presents arguments that would obviate these rejections if asserted in a first Official Communication in connection with such continuation application.

In the Office Action, the Examiner stated that claims 3-7, 9, 12, 13 and 29 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. §112, second paragraph, set forth in this office action. The Examiner further stated that claims 18-23, 25-28 and 38-42 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form. The Applicant kindly thanks the Examiner for identifying allowable subject matter.

Although claim 25 is indicated by the Examiner as allowable on page 7 of the Office Action, it appears that this indication is in error, as claim 25 was subject to rejection on page 6, line 5. Applicant respectfully requests clarification if claim 25 was indeed considered to be directed to allowable subject matter.

Claims 1-16, 29, 30, and 44 stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter.

The rejection of dependent claims 2-16 under 35 U.S.C. §112, second paragraph stems solely from the rejection of independent claim 1 for purportedly being indefinite. Independent claim 1 has been amended to obviate this rejection. As such, the Applicant respectfully requests withdrawal of the rejection of claims 1-16 under 35 U.S.C. §112, second paragraph.

Claims 29 and 30 have been amended to overcome the rejection under 35 U.S.C. §112, second paragraph. As such, the Applicant respectfully requests withdrawal of the rejection of claims 29 and 30. Claim 44 has been canceled, rendering the rejection under 35 U.S.C. §112, second paragraph moot.

Claims 1, 16, 17, 30-35, 43, and 45 stand rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 6,280,462 to *Hauser et al.* (hereinafter "*Hauser*").

Notwithstanding the amendments to the claims placing them in condition for allowance, the §102(b) rejection of claims 1, 16, 17, 30-35, 43 and 45 is improper as *Hauser* fails to anticipate the claims as originally presented.

To anticipate a claim, the reference must teach every element of the claim. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Therefore, all claim elements, and their limitations, must be found in the prior art reference to maintain a rejection based on 35 U.S.C. §102. Applicant respectfully submits that *Hauser* does not teach each and every element of independent claims 1, 17, 32, and 43 as originally presented, and therefore fails to anticipate these claims.

Hauser discloses an embodiment of an implantable pulse generator that includes a thermal sensor. (Col. 5, Lines 5-21). Hauser discloses that the pulse generator will not

shock unless the sensor indicates that the pulse generator housing is at body temperature. (Id.).

Respectfully, one of ordinary skill in the art would not consider body heat to constitute a non-electrophysiological signal associated with a <u>cardiac</u> source. For example, once heat is produced in the body, this heat would not be associated with any particular organ (e.g., the heart). Moreover, considering that the housing of *Hauser's* pulse generator is not placed in contact with cardiac tissue, the thermal sensor in the housing would not be able to associate a temperature measurement with heat generated by the heart. (See Figs. 6 and 15; see also Col. 4, Lines 52-56).

Each of Applicant's independent claims 1, 17, 32, and 43 include, among other limitations, some variation of receiving signals associated with a non-electrophysiological cardiac source. (Emphasis added). The Applicant respectfully submits that *Hauser* does not teach receiving signals associated with a non-electrophysiological cardiac source. As such, *Hauser* does not teach each and every element and limitation of independent claims 1, 17, 32 and 43.

Dependent claims 16, 30-31, 33-35, and 45, which are dependent from independent claims 1, 17, 32, and 43, respectively, were also rejected under 35 U.S.C. §102(b) as being unpatentable over *Hauser*. While Applicant does not acquiesce with the particular rejections to these dependent claims, it is believed that these rejections are now moot in view of the remarks made in connection with independent claims 1, 17, 32, and 43. These dependent claims include all of the limitations of the base claim and any intervening claims, and recite additional features which further distinguish these claims from the cited reference. Therefore, dependent claims 16, 30-31, 33-35, and 45 are also not anticipated by *Hauser*.

For at least these reasons, Applicant respectfully submits that the rejection of claims 1, 16, 17, 30-35, 43, and 45 as being anticipated by *Hauser* is not sustainable.

Claims 1, 2, 8, 10, 11, 14, 15, 17, 24, 25, 31, 32, 33, 36, 37, and 43-45 stand rejected under 35 U.S.C. §102(e) as being anticipated by WO 03/020367 to *Nelson et al.* (hereinafter

"Nelson"). The Applicant respectfully points out that Nelson is not a qualified reference under 102(e) because Nelson's international application does not designate the U.S. However, the reference may be a qualified reference under §102(a). In the event that the Nelson reference were shown to be a qualified reference under §102(a), the Applicant respectfully submits that Nelson would not anticipate claims 1, 2, 8, 10, 11, 14, 15, 17, 24, 25, 31, 32, 33, 36, 37, and 43-45, for at least the following reasons.

Nelson teaches an implantable device for diagnosing and treating myocardial ischemia. Nelson discloses that its device detects both electrical signals (ECG) and dynamic mechanical activity signals from the heart and uses both to diagnose myocardial ischemia. (Page 3, Lines 1-28). Nelson teaches that each of the signals must satisfy a criterion for an ischemia diagnosis to be made and therapy delivered. (See Figs. 9-11).

Although *Nelson* teaches the use of both ECG and dynamic mechanical activity signals to diagnose ischemia, *Nelson* does not disclose a step in this process where the dynamic mechanical activity signal is used to verify that the ECG signal is truly a cardiac signal. While *Nelson's* dynamic mechanical activity signal may corroborate the diagnoses of *Nelson's* ECG signal, *Nelson* does not teach using the dynamic mechanical activity signal to verify that the ECG signal is indeed a cardiac signal.

Each of Applicant's independent claims 1, 17, 32, and 43 include, among other limitations, some variation of verifying that the electrocardiogram signals comprise a cardiac signal using the non-electrophysiological signal. The Applicant respectfully submits that *Nelson* clearly does not teach verifying that electrocardiogram signals comprise a cardiac signal using a non-electrophysiological signal. As such, *Nelson* does not teach each and every element and limitation of independent claims 1, 17, 32, and 43.

Dependent claims 2, 8, 10, 11, 14, 15, 24, 25, 31, 33, 36, 37, 44, and 45, which are dependent from independent claims 1, 17, 32 and 43, respectively, were also rejected under 35 U.S.C. §102(e) as being unpatentable over *Nelson*. While Applicant does not acquiesce with the particular rejections to these dependent claims, it is believed that these rejections are now moot in view of the remarks made in connection with independent claims 1, 17, 32,

and 43. The rejections to the dependent claims would be similarly moot if they were made under §102(a). These dependent claims include all of the limitations of the base claim and any intervening claims, and recite additional features which further distinguish these claims from the cited reference. Therefore, dependent claims 2, 8, 10, 11, 14, 15, 24, 25, 31, 33, 36, 37, 44, and 45 are also not anticipated by *Nelson*.

For at least these reasons, Applicant respectfully submits that the rejection of claims 1, 2, 8, 10, 11, 14, 15, 17, 24, 25, 31, 32, 33, 36, 37, and 43-45 as being anticipated by *Nelson* is not sustainable.

In several places in the Office Action, the Examiner indicates that various references, including the *Hauser* and *Nelson* references, were "admitted prior art." It is to be understood that the Applicant has not admitted that any references are indeed prior art and makes no such admission in this response. In regard to all references listed in the Applicant's Information Disclosure Statement (IDS), the Applicant's IDS stated that "[n]o representation is made that a reference is "prior art" within the meaning of 35 U.S.C. §§ 102 and 103 and Applicants reserve the right, pursuant to 37 C.F.R. § 1.131 or otherwise, to establish that the reference(s) are not "prior art." (Page 2).

It is to be understood that the Applicant does not acquiesce to the Examiner's characterization of the asserted art or the Applicant's claimed subject matter, nor of the Examiner's application of the asserted art to the Applicant's claimed subject matter. Moreover, the Applicant does not acquiesce to any explicit or implicit statements or conclusions by the Examiner concerning what would have been known to one of ordinary skill in the art, what is Applicant's prior art, officially noticed facts, and the like. The Applicant respectfully submits that a detailed discussion of each of the Examiner's rejections beyond that provided above is not necessary, in view of the clear absence of teaching of various features recited in the Applicant's pending claims. The Applicant, however, reserves the right to address in detail the Examiner's characterizations, conclusions, and rejections in future prosecution.

Authorization is given to charge Deposit Account No. 50-3581 (GUID.608PA) any necessary fees for this filing. If the Examiner believes it necessary or helpful, the undersigned attorney of record invites the Examiner to contact him at to discuss any issues related to this case.

Respectfully submitted,

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